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EXAMINER	
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ART UNIT	PAPER NUMBER
1611	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,326	HASENZAHL ET AL.	
	Examiner	Art Unit	
	RACHAEL E. WELTER	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 November 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,6 and 7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6 and 7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Status

Claims 1-3 and 6-7 are pending. Claims 4-5 are cancelled.

Acknowledgements

Receipt of the amendment and remarks/arguments filed on 11/2/10 is acknowledged.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1-2 rejected under 35 U.S.C. 102(b) as being anticipated by Shimizu et al (US Publication No. 2002/0102369) as evidenced by Scholz et al (US Patent No. 6,951,642) is maintained.

Shimizu et al teach a cellulose ester dope composition comprising Aerosil R 972V and benzoin (see paragraph 0272); example 21). As evidenced by Scholz et al, benzoin is a polymerization initiator used in moisturizing skin treatment compositions that aids in the copolymerization of (meth) acrylate and various comonomers (column 9, lines 53-61). Furthermore, as evidenced by the instant specification, Aerosil R 972V is a hydrophobic highly disperse silicon dioxide type that is particularly suitable for the

composition (pg. 11, lines 19-27). According to the instant specification, Aerosil R 972V exhibits the instant tamped density, water-wettable contents, and BET surface area (see Table 6, pg. 24).

Response to Arguments

Applicant's arguments filed 11/2/10 have been fully considered but they are not persuasive.

Applicant argues that the instant claims have been amended to recite a flowable composition. Applicant submits that Shimizu does not mention a flowable cosmetic or pharmaceutical composition.

In response to applicant's arguments, it is noted that example 21 of Shimizu, as pointed out by the examiner in the rejection above is directed to a dope composition not a film. According to Shimizu, the dope composition is incorporated in a pressurized sealed vessel and stirred. Furthermore, the composition is filtered before being casted and dried (see column 47, lines 26-67). Thus, the dope composition appears to be a liquid and capable of having flowable characteristics. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d

1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433.

As such, it is the examiner's position that the rejection should be maintained for the reasons stated above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claim 3 rejected under 35 U.S.C. 103(a) as being unpatentable over Shimizu et al (US Publication No. 2002/0102369) as evidenced by Scholz et al (US Patent No. 6,951,642) is maintained.

The disclosure of Shimizu et al is discussed above.

Shimizu et al do not teach an amount of Aerosil R 972V that is from 0.01 to 30 wt.% but rather teach an amount that overlaps with the instant amount. Shimizu et al teach that the silicon dioxide particles can be present in an amount of 0.005-0.3 wt.% (column 33, lines 45-48).

However, it would have been obvious to an artisan of ordinary skill at the time the invention was made to modify and optimize the amount of Aerosil R 972V in the composition of Shimizu et al. Optimization of parameters is a routine practice that would be obvious to a person of ordinary skill in the art to employ and reasonably expect success. One would have been motivated to determine the optimal amount of each ingredient in order to best achieve the desired results, which ultimately depends on the desired matting effect and transparency. See *In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) &* MPEP 2144.05.

Response to Arguments

Applicant's arguments filed 11/2/10 have been fully considered but they are not persuasive.

Applicant argues that a reference must teach each and every element required by the claims. Applicant argues that claim 1 is clearly directed to a "flowable" pharmaceutical or cosmetic formulation. Applicant submits that the claimed subject matter is clearly not a cellulose ester film for use as a protective film for a polarizing plate as taught in Shimizu. Applicant submits that the silica employed by Shimizu is a filler and does not aid to facilitate flowability. Applicant fails to see why the composition of Scholz is properly combined with Shimizu. Neither Scholz nor Shimizu desires a flowable powder suitable for tableting or placement in a capsule. Furthermore, applicant does not see how optimization of Shimizu would lead to having a flowable composition with the claimed tamped density range.

The examiner acknowledges that Shimizu is directed to a protective film for a polarizing plate. However, example 21 of Shimizu, as pointed out by the examiner in the rejection above is directed to a dope composition not a film. According to Shimizu, the dope composition is incorporated in a pressurized sealed vessel and stirred. Furthermore, the composition is filtered before being casted and dried (see column 47, lines 26-67). Thus, the dope composition appears to be a liquid and capable of having flowable characteristics. See above *In re Best*.

Additionally, applicant's argument that the silica is employed for a different purpose than the prior art is not persuasive. It is noted that the instant claims are directed to a composition and as long as the prior art suggests all the components of

the compositions (Aerosil R972V), the components are capable of performing an intended function. According to MPEP 2111.02 (II), statements reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference between the claimed invention and the prior art. If so, the recitation serves to limit the claim. Applicant has done nothing to structurally distinguish the instant silica's function and has failed to claim a tablet or capsule in claims 1-3. The features upon which applicant relies (i.e., tablets, capsules) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Regarding applicant's argument over Scholz, it is noted that Scholz is only combined with Shimizu to provide evidence that benzoin is a pharmaceutical or cosmetic compound. Furthermore, since Shimizu teaches Aerosil R972V in an amount of 0.005-0.3 wt.% that overlaps with the instant amount, it would have been obvious to use an amount within the instant range (0.01-30 wt.%) as part of routine optimization. One would have been motivated to optimize the amount of silica in Shimizu depending on the desired matting effect and transparency. Methods of determining appropriate component percentages are well-known in the art, and one of ordinary skill in the art would have arrived at the appropriate percentages via routine experimentation. Manipulation of relative amounts of formulation components do not support the patentability of subject matter encompassed by the prior art, unless there is evidence indicating unexpected results. Moreover, even though applicant argues that the

optimization of the silicon dioxide would change the instant tamped density, it is the examiner's position that the instant tamped density is an intrinsic property of Aerosil R972V. This is evidenced by applicant's own specification (see Table 6, pg. 24).

As such, it is the examiner's position that the rejection should be maintained for the reasons stated above.

The rejection of claims 1-3 rejected under 35 U.S.C. 103(a) as being unpatentable over Sebillotte-Arnaud et al (US Publication No. 2002/0039976) is maintained.

Sebillotte-Arnaud et al teach a cleansing composition comprising at least one foaming surfactant, at least one hydrophobic silica, and at least one oxyalkylenated compound in a physiologically acceptable aqueous medium (paragraph 0011). According to Sebillotte-Arnaud et al, the hydrophobic silica have a specific surface area ranging from 50-500 m^2/g and a compacted density preferably from 50-150 g/L (paragraph 0021; Table 1). Sebillotte-Arnaud et al further teach that the hydrophobic silica can be in an amount from 1-15 wt.% (paragraph 0018). Additionally, Sebillotte-Arnaud et al suggest that Aerosil R 972 can be used in the composition.

Although Sebillotte-Arnaud et al teach that the composition can comprise Aerosil R 972, Sebillotte-Arnaud et al do not teach a composition comprising Aerosil R 972V, which meets the instant density requirements. It is noted from the instant specification that a difference between Aerosil R 972V and Aerosil R 972 is the density (see Table 6, pg. 24).

However, it would have been obvious to an artisan of ordinary skill at the time the invention was made to use a hydrophobic silica, such as Aerosil R 972V in the composition of Sebillotte-Arnaud et al. One would have been motivated to do so depending on the silica's desired compacted density and because Sebillotte-Arnaud et al suggest that its silica can have a compacted density in a range from 50-150 g/L, which overlaps with the instant range.

Regarding the limitation, "wherein the silicon dioxide contains a maximum of 3.0 wt.% water-wettable contents," it is noted that Sebillotte-Arnaud et al teach hydrophobic silica. Furthermore, the instant specification provides evidence that Aerosil 972 exhibits water-wettable contents of 3 wt.% (see pg. 24, Table 6).

Response to Arguments

Applicant's arguments filed 11/2/10 have been fully considered but they are not persuasive.

Applicant argues that there is no mention of tablet or capsules, flowability of granular materials or hardness of tablets in Sebillotte-Arnaud. Additionally, applicant argues that compaction is employed for the purposes of applicant's invention and that grinding of the compacted product is required. Applicant further submits that hydrophobic silica only thickens the prior art's composition and is not an active ingredient. Applicant argues that it is not clear why a more dense silica would be desired for Sebillotte-Arnaud's purposes. Applicant submits that the present claims are

believed to be commensurate in scope with the unexpected results presented in the specification.

In regard to applicant's argument that there is no mention of tablets, capsules, etc in Sebillotte-Arnaud, it is noted that the instant claims 1-3 are not drawn to specific oral dosage forms, such as tablets, capsules, etc. The features upon which applicant relies (i.e., tablets, capsules, grinding of the compacted product, etc) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, even though applicant amended the claims to a “flowable” composition, it is noted that Sebillotte-Arnaud teaches the combination of hydrophobic silica and oxyalkylenated compound in their composition makes it possible to prepare foaming products which flow under their own weight (see paragraph 0012).

Although applicant argues that the silicon dioxide is not an active ingredient, it is noted that the silicon dioxide in the instant claims is not defined as an active ingredient. Rather, the silicon dioxide in the instant claims is distinguished from the active or cosmetic compound. Applicant has also not defined an "active pharmaceutical or cosmetic compound” in their specification.

The examiner also disagrees with applicant that higher more dense, low structured silica are not envisioned by the teachings of Sebillotte-Arnaud. Sebillotte-Arnaud suggests a range of density (50-150g/L) that overlaps with the claimed density of 90-400g/L. According to MPEP 2144.05, in the case where the claimed ranges

"overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. *In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990)* (The prior art taught carbon monoxide concentrations of "about 1-5%" while the claim was limited to "more than 5%." The court held that "about 1-5%" allowed for concentrations slightly above 5% thus the ranges overlapped.); *In re Geisler, 116 F.3d1465, 1469-71, 43 USPQ2d 1362, 1365-66 (Fed. Cir. 1997).* Additionally, the specification was only used to gain a better understanding of the invention and to determine the differences between AEROSIL R972V and AEROSIL R972. In this case, it is clear from the specification and applicant's arguments that a difference between the AEROSIL products is density. The specification was not relied on for any specific teachings and all the limitations of the instant claims are suggested in the teachings of Sebillotte-Arnaud.

Applicant's alleged unexpected results are acknowledged. However, it is the examiner's position that a prima facie case of obviousness has been established. Since Sebillotte-Arnaud teaches a cosmetic formulation comprising AEROSIL R972, which has a water-wettable contents of 3 wt.% and suggests silica with a density of 50-150 g/L, the different outcomes, such as tablet hardness and disintegration time in Tables 7-8 would be intrinsic. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. *In re Wiseman*, 596 F.2d 1019, 201 USPQ 658 (CCPA 1979).

Furthermore, even if applicant is arguing that the outcomes of the AEROSIL products would be unexpected, these outcomes are not commensurate in scope with

instant claims 1-3. According to MPEP 716.02, whether the unexpected results are the result of unexpectedly improved results or a property not taught by the prior art, the "objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support." It is noted that Tables 7 and 8 in the specification, which show the different properties of the AEROSIL products, are all drawn to properties of tablets. However, applicant is not claiming a tablet or solid formulation in claims 1-3 but rather just a flowable composition. Thus, in order to be commensurate in scope with instant claim1-3, applicant needs to narrow their scope and limit the formulations to a tablet.

As such, it is the examiner's position that the rejection should be maintained for the reasons stated above.

New Rejections

The following rejection constitutes new grounds for rejection necessitated by amendment.

The rejection of claims 1-3 and 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Staniforth et al (US Patent No. 6,471,994; Published 10/29/2002) in view of Jang (US Patent No. 4,590,062; Published 5/20/1986).

Staniforth et al teach a microcrystalline cellulose based-excipient for use in the manufacture of pharmaceuticals including tablets and capsules (column 1, lines 14-18; column 18, lines 62-65; abstract). The tablets also include active ingredients (column 5, lines 56—column 6, lines 1-2). The excipient comprises a particulate agglomerate of

coprocessed microcrystalline cellulose and from 0.1-20 wt.% silicon dioxide by weight of the microcrystalline cellulose (column 5, lines 20-30). According to Staniforth et al, all forms of silicon dioxide can be used with a preferred surface area from about 50 m^2/g—500 m^2/g (column 10, lines 18-52). Additionally, a preferred silicon dioxide is Aerosil with a density of 20 g/L to about 100 g/L and a moisture content of 0.5-2.5%. (column 10, lines 53-62; column 13, lines 45-48). The examiner is interpreting the moisture content in Staniforth et al to be the water-wettable content of the instant claims. Staniforth et al also teach that a conventional amount of silicon dioxide in a tablet is 0.1-0.5 wt.% (column 10, lines 8-10).

Although Staniforth et al teach that all forms of silicon dioxide can be used; Staniforth et al do not explicitly teach that its silicon dioxide is hydrophobic.

Jang teaches 0.05-3 wt.% hydrophobic fumed silica including Aerosil R972 in tablets (column 13, lines 39-60; column 16, lines12-19). According to Jang, the silicon dioxide provides controlled release tablets with better control of release, slower release if desired, and improved physical integrity in aqueous environments such as the digestive tract (column 16, lines 12-19).

Therefore, it would have been obvious to an artisan of ordinary skill at the time the invention was made to utilize hydrophobic silicon dioxide in the tablets or capsules of Staniforth et al. One would have been motivated to do so since Jang suggests that hydrophobic silicon dioxide aids in achieving desirable release rates and more specifically slower release rates. Thus, if an artisan desired a slower release rate for a

particular patient population, one would have a reasonable expectation of success to incorporate silicon dioxide in its dosage forms.

Conclusion

Claims 1-3 and 6-7 are rejected. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHAEL E. WELTER whose telephone number is (571) 270-5237. The examiner can normally be reached 7:30-5:00 Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached at 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

REW

/David J Blanchard/
Primary Examiner, Art Unit 1643